

CLAIMS

- 1 1. A therapeutic delivery system for a host comprising:
 - 2 a therapeutic agent; and
 - 3 a sacromastigophoric organism containing said therapeutic agent and a recombinant lytic factor.
- 1 2. The system of claim 1 wherein said therapeutic agent is selected from the group consisting of:
 - 3 a gene, an artificial chromosome, magnetic species, radioactive species, vitamins, nanocrystals, drugs, and prodrugs.
- 1 3. The system of claim 2 wherein said therapeutic agent is a gene selected from the group consisting of: a native organism gene, a host gene, a pathogen gene, a polymorph of a host gene, a polymorph of a pathogen gene, a virus, and a provirus.
- 1 4. The system of claim 1 wherein the said organism is selected from the group consisting of Trypanosoma, Plasmodium, Amoeba, Giardia, Entamoeba, and Leishmania.
- 1 5. The system of claim 1 wherein said lytic factor is selected from the group consisting of: Hpr, trialysin, Bad and Bax.

1 6. The system of claim 5 wherein said trypanosome is
2 *Trypanosoma brucei*.

1 7. The system of claim 1 wherein said recombinant lytic factor is
2 upregulated by a promoter responsive to an induction species exogenous to
3 both said organism and said host.

1 8. The system of claim 7 wherein said induction species is an
2 antibiotic.

1 9. The system of claim 1 further comprising a gene encoding a
2 small interfering RNA related to said therapeutic agent.

1 10. The system of claim 1 wherein said therapeutic agent is a
2 diagnostic marker.

1 11. A therapeutic delivery system for a host comprising:
2 a trypanosome organism containing a recombinant lytic factor
3 upregulated by a promoter responsive to an induction species exogenous to
4 both said organism and said host.

1 12. The system of claim 11 further comprising an expression
2 cassette having a translatable gene coding for a polypeptide.

1 13. The system of claim 11 wherein said trypanosome is
2 *Trypanosoma brucei*.

1 14. The system of claim 12 wherein said gene codes green
2 fluorescent protein.

1 15. The system of claim 12 wherein said expression cassette further
2 comprises a plurality of translatable genes.

1 16. A process for producing a sacromastigophoric organism for
2 delivery of a therapeutic agent comprising the steps of:
3 culturing sacromastigophoric organisms that have been transfected with
4 an expression cassette induced by a first exogenous species, the cassette
5 comprising:

6 a first construct having a first promoter controlling expression of a lytic
7 protein.

1 17. The process of claim 16 wherein said organism is selected from
2 the group consisting of:
3 Trypanosoma, Plasmodium, Amoeba, Giardia, Entamoeba, and
4 Leishmania.

1 18. The process of claim 16 wherein said organism is a
2 *Trypanosoma*.

1 19. The process of claim 18 wherein said organism is *Trypanosoma*
2 *brucei*.

1 20. The process of claim 16 further comprising a second construct
2 encoding genes comprising a second promoter, a polymerase termination
3 sequence, and a preselected gene.

1 21. The process of claim 20 wherein said second construct further
2 comprises a ribosome binding site and a poly A tail.

1 22. The process of claim 20 further comprising a gene conferring
2 resistance to a second exogenous species.

1 23. The process of claim 16 wherein said first promoter is induced
2 by said exogenous species.

1 24. The process of claim 16 wherein said first exogenous species is
2 an antibiotic.

1 25. The process of claim 16 further comprising the step of
2 packaging a non-nucleic acid therapeutic agent in said organism.

1 26. A process for producing a sacromastigophoric organism for
2 delivery of a therapeutic agent comprising the steps of:

3 culturing trypanosome organisms that have been transfected with an
4 expression cassette induced by a first exogenous species, the cassette
5 comprising:

6 a first construct having a promoter induced by said first exogenous
7 species controlling expression of haptoglobin related protein.

1 27. The process of claim 26 further comprising a second construct
2 encoding genes comprising a second promoter, a polymerase termination
3 sequence, and a preselected gene.

1 28. The process of claim 27 wherein said second construct further
2 comprises a ribosome binding site and a poly A tail.

1 29. The process of claim 27 further comprising a gene conferring
2 resistance to a second exogenous species.

1 30. The process of claim 26 wherein said first exogenous species is
2 an antibiotic.

1 31. The process of claim 22 wherein said second exogenous species
2 is an antibiotic effective against a wild trypanosome.

1 32. A method of treating or preventing a disease in a host
2 comprising the steps of:

3 administering to said host a therapeutic amount of a sacromastigophoric
4 organism that has been transfected with an expression cassette induced by an
5 exogenous species signal, said cassette comprising a first construct having a
6 promoter controlling expression of lytic protein;

7 allowing sufficient time for said organism to infect said host; and

8 administering said exogenous species to induce lysis of said organism.

1 33. The method of claim 32 wherein said organism is selected from
2 the group consisting of:

3 Trypanosoma, Plasmodium, Amoeba, Giardia, Entamoeba, and
4 Leishmania.

1 34. The method of claim 32 wherein said organism is *Trypanosoma*
2 *brucei*.

1 35. The method of claim 32 wherein said exogenous species is an
2 antibiotic.

1 36. The method of claim 32 further comprising the step of
2 introducing into said organism a second construct encoding genes comprising:
3 a second promoter, a polymerase termination sequence, integrase, and a
4 preselected gene.

1 37. The method of claim 36 wherein said preselected gene encodes
2 a host gene, a pathogen gene, a polymorph of a host gene, a polymorph of a
3 pathogen gene, a virus, and a provirus.

1 38. The method of claim 32 further comprising the step of
2 packaging a non-nucleic acid therapeutic agent into said organism prior to
3 administering said organism to said host.

1 39. The method of claim 38 wherein said non-nucleic acid
2 therapeutic agent is selected from a group consisting of: magnetic species,
3 radioactive species, vitamins, nanocrystals, drugs, and prodrugs.

1 40. The use of an intracellular parasite containing a recombinant
2 exogenous species induced lytic factor to deliver a therapeutic agent to a host.

1 41. An organism obtainable by the process as claimed in claim 16.

- 1 42. A commercial package comprising a therapeutic agent delivery system
- 2 according to claim 1 as an active ingredient with instructions for the use thereof
- 3 as a therapeutic.